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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,530	07/24/2000	Richard Sackler	200.93185C2C	5659

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/27/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/624,530	SACKLER ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 6-23 are pending.

The Arguments filed 1/6/03, Paper No. 18, are persuasive to overcome the Double Patenting Rejections in the previous Office Action. A further examination by the Examiner of the applications and patent by which the double patenting rejection was made in the previous Office Action, resulted in the withdrawal of the double patenting over the co-pending applications and patent.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/6/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "protein-derived materials" in claims 13 (line 3) is vague and indefinite, as the metes and bounds of this claim are unascertainable. What is a protein derived material? Is it

a protein? It is an amino acid? What is it? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

(ii) The term "lower" in claim 18 (line 2) is a relative term which renders the claim indefinite. The term "lower" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does lower encompass C18? C50?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-7, 9, 11-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Paradissis et al. (5,133,974).

Paradissis et al. teach extended release pharmaceutical formulations. A 24 hour time period is disclosed as the extended release. The formulation comprises a mixture of 0-50% of an immediate release particle containing a drug, substrate and binder, coated with talc, and up to 100% of an extended release particle that coats the immediate release particle with a dissolution modifying system containing plasticizers and a film forming agent. Narcotics, such as morphine, are disclosed as drugs. The drug adheres to an inert spherical substrate particle through a binding agent, which is applied by a solvent. It is exemplified that inert spherical substrate particles are placed in a suitable coating pan to which the drug is added and the binder solution is then sprayed onto the mixture. Hydroxypropylmethyl cellulose, hydroxypropyl cellulose, ethylcellulose, acrylic acid copolymers and methyacrylic acid copolymers are disclosed as

binders. Water insoluble hydrophobic plasticizers disclosed include castor oil, propylene glycol and mixtures thereof. Ethyl cellulose, methyl cellulose, acrylic and methacrylic acid copolymers are disclosed as film forming polymers. See Col. 4, line 26-Col. 8, line 26.

Thus, the instant invention and Paradissis both teach extended release drug formulations comprising a drug coated with matrix spheroids that are coated with an acrylic copolymer or ethylcellulose and comprise hydroxylower alkylcellulose or acrylic polymer, which is further coated with a controlled release matrix comprising alkylcellulose or cellulose ether and a hydrocarbon and polyalkylene glycol.

The Examiner respectfully points out that a compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Thus, the extended release pharmaceutical formulation of Paradissis et al. must exhibit the same properties as that recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. as applied to claims 6-7, 9, 11-19 above.

The instant invention is directed toward a method for treating pain in humans for a time period of about 24 hours, comprising preparing a solid, controlled-release oral dosage form, the

dosage form comprising an analgesically effective amount of an opiod analgesic, wherein the analgesic is contained in a controlled-release matrix.

Paradissis et al. is applied as discussed above. Morphine, hydromorphone, and oxycodone are taught as interchangeable narcotics for use in the invention. Amounts of at least 50mg per dosage form are disclosed. The reference lacks an exemplification of hydromorphone, oxycodone, and dosage amounts. See Col. 4, lines 26-59; Col. 5, lines 13-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydromorphone or oxycodone for morphine in Paradissis et al. because of the expectation of achieving equivalent pain relief.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the formulations of Paradissis et al. as comprising at least 50mg of drug because of the expectation of achieving dosage amounts that are effective to treat different levels and forms of pain, and different weight amounts of patients. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant argues, "The controlled release particles described in the '974 patent do not encompass controlled release matrix formulations. The '974 patent describes extended release formulations comprising. . .In contrast, the present claims recite, in pertinent part, an opiod analgesic contained in a controlled release matrix, as opposed to the coated immediate release drug particles of Paradissis et al". This argument is not persuasive. The Examiner respectfully points out that '974 does teach a controlled release matrix formulation. The controlled release

matrix formulation of '974 comprises an immediate release particle comprising an opiod narcotic and encompassed by an inert spherical substrate and a dissolution modifying system containing plasticizers and a film forming agent that encompasses the immediate release particle. The Examiner respectfully reminds Applicant that Applicant is her or her own lexicographer. Thus, while Paradissis et al. do not explicitly use the term "controlled release matrix formulation", Paradissis et al. do teach the same formulation. Furthermore, for clarity, the Examiner further points out that the coated immediate release drug particles of Paradissis et al. are not being equated to the controlled release matrix of the instant invention. The combination of the immediate release drug particles and the dissolution modifying system of Paradissis et al. are combined to produce their extended release formulation. The Examiner further points out that a the claims are directed to a method of treating pain in human for a time period of about 24 hours comprising preparing a solid, controlled release oral dosage form, the dosage form comprising an opiod analgesic and being contained in a controlled release matrix, wherein the form and controlled release matrix are further defined in dependent claims. Any properties exhibited by or benefits provided the formulation are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches extended release formulations containing the same components as instantly claimed, which would inherently meet Applicant's functional language and the recitation of a "controlled release

matrix". Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Applicant argues, "regardless of the structure of the dosage forms recited in the claimed methods, the Paradissis reference does not exemplify opiod analgesic formulations". This argument is not persuasive. First, the Examiner respectfully directs Applicant to claim 22 of Paradissis et al. wherein morphine is disclosed. Second, the Examiner respectfully directs Applicant to claim 2 of Paradissis et al, wherein narcotics are disclosed as the drug, and Col. 4 of the specification discloses, aside from morphine, oxycodone and hydromorphone, as the narcotics.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
April 30, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

5/4/03